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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/657,249

09/09/2003

Kim R. Rogers

ROGERS1

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1444 7590 08/24/2007
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EXAMINER

NAFF, DAVID M

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

08/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/657,249	Applicant(s) ROGERS ET AL.	
	Examiner David M. Naff	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-6, 8-15 and 19 is/are pending in the application.
- 4a) Of the above claim(s) 2-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-15 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for
5 continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/1/07 has been entered.

An amendment of 6/1/07 amended claims 8-11, 14 and 15, added new
10 claim 19, and canceled claims 1, 7 and 16-18.

Claims in the case are 2-6, 8-15 and 19.

Claims 2-6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the
15 restriction (election) requirement in the reply filed on 4/5/06.

Claims examined on the merits are 8-15 and 19.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

20 Claims 8-15 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is unclear how the bag is defined by being opened. The
25 bag being opened to expose the acetylcholinesterase to the inhibitor

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is involved in a process of using the detector. The detector does not contain the bag while open before use in a process of detecting. If the claim intends the bag to be capable of being opened to expose the acetylcholinesterase to the inhibitor, the claim should be amended by inserting --- capable of being --- after "is" in line 5.

Claim 15 is confusing by not having antecedent basis for "the sol-gel particles". Claim 1 does not require sol-gel particles.

Where recited in the claims, "enzyme" is confusing since acetylcholinesterase is inherently an enzyme.

10 ***Claim Rejections - 35 USC § 103***

Claims 9, 10 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kok et al (J. Biomater. Sci. Polymer Edn, Vol 12, No. 11, pp. 1161-1176 (2001)) in view of Strobel et al (5,766,473).

The claims are drawn to a detector for detecting at least one of organophosphorus or carbamate consisting of acetylcholinesterase immobilized in a sol-gel or membrane, wherein the acetylcholinesterase is inhibited by the organophosphorus or carbamate. The sol-gel or membrane is packaged in a semipermeable material that controls access of acetylcholinesterase inhibitors. The package can be a semipermeable polyethylene bag which is opened after exposure to the inhibitor to commence the assay.

Kok et al disclose acetylcholinesterase and choline oxidase immobilized in a membrane for use as a biosensor.

Strobel et al disclose storing enzyme-loaded membranes in a polyethylene bag (col 33, lines 43-45).

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It would have been obvious to store the membrane containing acetylcholinesterase disclosed by Kok et al in a polyethylene bag as suggested by Strobel et al storing an enzyme-containing membrane in a polyethylene bag. It would have been obvious to use a semipermeable polyethylene bag when desiring to contact the acetylcholinesterase with the inhibitor while in the bag. Using the bag for both storage of the immobilized acetylcholinesterase and contact the inhibitor would have been obvious to obtain use of the bag for both functions. Acetylcholinesterase is not oxygen sensitive, and when storing acetylcholinesterase in the bag protecting from oxygen as disclosed by Strobel et al would obviously not be required. It would have been further obvious to omit choline oxidase from the membrane of Kok et al when the function of the choline oxidase is not needed. The acetylcholinesterase of Kok et al will inherently be inhibited by organophosphorus or carbamate compounds.

Claim Rejections - 35 USC § 103

Claims 8 and 14 are is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 9, 10 and 19 above, and further in view of Stanford et al and Avnir et al.

Claim 8 requires the acetylcholinesterase to be immobilized in a sol-gel, and claim 14 requires the sol-gel to be in a tube.

Stanford et al disclose acetylcholinesterase immobilized in a sol-gel film on electrodes. For example, see claim 9.

Avnir et al disclose entrapping enzymes in a sol-gel glass (paragraph bridging cols 4 and 5) for use as a biosensor (col 5, lines

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14-15). The sol-gel containing the immobilized enzyme can be formed in a tube (col 7, line 17).

When modifying Kok et al as suggested by Strobel et al as set forth above, it would have been obvious to substitute for the membrane of Kok et al a sol-gel as suggested by Stanford et al and Avnir et al for immobilizing acetylcholinesterase. It would have further been obvious to form the sol-gel in a tube as suggested by Avnir et al forming the sol-gel in a tube.

Claim Rejections - 35 USC § 103

10 Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 8 and 14 above, and further in view of Charych et al (6,485,987 B1).

The claim requires the sol-gel to be a glass prepared from tetramethylorthosilicate.

15 Charych et al disclose preparing a sol-gel glass from tetramethylorthosilicate (paragraph bridging cols 2 and 3) for use as a detection means (col 3, line 43).

When modifying Kok et al as suggested by references as set forth above, it would have been obvious to produce the sol-gel as a glass using tetramethylorthosilicate as suggested by Charych et al.

Claim Rejections - 35 USC § 103

20 Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 11 above, and further in view of Khue et al (5,624,831).

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The claims required the acetylcholinesterase in the sol-gel to be stabilized with a sugar, which can be trehalose.

Khue et al disclose that trehalose is a sugar used to stabilize enzymes (col 3, line 31), and using trehalose to produce stabilized
5 acetylcholinesterase (paragraph bridging cols 3 and 4).

When modifying Kok et al as suggested by references as set forth above, it would have been obvious to use trehalose to stabilize acetylcholinesterase as suggested by Khue et al.

Claim Rejections - 35 USC § 103

10 Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 8 and 14 above, and further in view of Magdassi et al (6,303,149 B1).

The claim requires sol-gel particles from 230-400 mesh.

Magdassi et al disclose sol-gel particles containing enzymes (col
15 2, lines 38 and 44-56, and col 3, lines 34-67).

When modifying Kok et al as suggested references above, it would have been obvious to produce the sol-gel as particles as suggested by Magdassi et al. Selecting a preferred particle size would have been a matter of choice within the skill of the art.

20 ***Response to Arguments***

The amendment urges that the polyethylene bag of Strobel et al is not semipermeable. However, it would have been obvious to use a semipermeable bag when desiring to contact the acetylcholinesterase with the inhibitor while the acetylcholinesterase is in the bag.

25 Acetylcholinesterase is not oxygen sensitive, and protecting from

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oxygen as disclosed by Strobelt et al would not be required when the enzyme is acetylcholinesterase.

Conclusion

Any inquiry concerning this communication or earlier

5 communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925.

10 The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



David M. Naff
Primary Examiner
Art Unit 1657

DMN

15 8/19/07